

CHRONOLOGY OF MAJOR ACTIVITIES DURING  
REGULATORY REVIEW. RELATING TO  
IND 17,123

Date

January 10, 1980	Submission to FDA	IND 17,123 for Sodium Phenylacetate
January 24, 1980	Letter from FDA	Acknowledged receipt of IND 17,123
February 19, 1980	Submission to FDA	Amended IND 17,123
March 17, 1980	Submission to FDA	Amended IND 17,123
March 17, 1980	Letter from FDA	Request for additional information
March 21, 1980	Submission to FDA	Response with requested information
May 12, 1980	Letter from FDA	Acknowledgment of receipt of information and request regarding labels.
June 6, 1980	Submission to FDA	Labels sent in response to request.
June 13, 1980	Submission to FDA	Amended IND 17,123
August 18, 1980	Submission to FDA	Amended IND 17,123
May 7, 1981	Submission to FDA	Annual Report
April 12, 1982	Submission to FDA	Annual Report
Undated	Letter from FDA	Request for additional information
June 8, 1982	Submission to FDA	Response to request information
November 3, 1982	Submission to FDA	Amended IND 17,123
February 2, 1983	Submission to FDA	Amended IND 17,123

May 24, 1983	Submission to FDA	Annual Report
November 28, 1983	Submission to FDA	Amended IND 17,123
July 23, 1984	Letter from FDA	
August 7, 1984	Submission to FDA	Amended IND 17,123
August 9, 1984	Submission to FDA	Amended IND 17,123
February 26, 1986	Letter from FDA	Letter re combined file IND 17,123 and 17,336

CHRONOLOGY OF MAJOR ACTIVITIES DURING  
REGULATORY REVIEW. RELATING TO  
IND 17,336

Date

March 17, 1980	Submission to FDA	IND 17,336 filed
April 2, 1980	Letter from FDA	Letter of acknowledgement
February 12, 1981	Letter from FDA	Request for additional information
Undated	Submission to FDA	Response to request for additional information
May 22, 1981	Submission to FDA	Annual Report
August 18, 1982	Submission to FDA	Amended IND 17,336
November 3, 1982	Submission to FDA	Letter regarding experimental protocol
February 3, 1983	Submission to FDA	Amended IND 17,336
April 22, 1982	Submission to FDA	Annual Report
August 17, 1984	Submission to FDA	Annual Report
October 1, 1984	Letter from FDA	Notification that IND transferred to different department
February 26, 1986	Letter from FDA	Letter re combined file IND 17,123 and 17,336



INDEX

NDA 19-530

Ucephan Oral Liquid

DATE	SUBJECT	LOCATION	
		VOL.	TAB
01/26/88	Letter from FDA granting seven years exclusivity.	1.1	OR.1